Appendix E : 510 (k) Summary

FEB 27 2002

1. General Information:

Company:	Depilase Group Ltd One Canada Square Canary Wharf London E14 5DY United Kingdom
Contact Person:	Dr. Mario Luca Russo
Preparation:	12-01-01
Device Trade Name:	DEPILASE YAG LASE PLUS Laser System
Common Name:	Long Pulsed Nd:YAG Surgical, Powered, Laser 79 –GEX 21 CFR 878-48

I. Description

The DEPILASE YAG LASE PLUS Laser System is based on Nd: YAG laser technology. Within the system, an optical cavity contains the Nd: YAG crystal, which is activated by means of the use of a flashlamp. After the cavity, a red diode aiming beam is reflected onto a coaxial beam path using a beamsplitter assembly. The combined therapeutic and aiming beams are guided down an optical fibre delivery system to a focusing handpiece. The laser is used in a non-contact mode.

The DEPILASE YAG LASE PLUS Laser System is designed with 5 major sub-systems:

a) A high voltage power supply which converts and rectifies the a.c. mains current to provide regulated power for the flashlamp simmer current and main triggering pulse.

b) A cooling system consisting of an internal water flow circuit together with water to air heat exchanger.

c) An Nd: YAG laser rod, capable of generating optical pulses at a frequency up to 3 Hz

d) An optical delivery system, interfacing the energy from the laser to the patient via an optical fibre and focusing handpiece.

e) The microprocessor based controller which regulates the functions of the laser and allows parameter selection by the user.

II. Intended Use

The DEPILASE YAG LASE PLUS Laser System is indicated for the coagulation and haemostasis of vascular lesions and the removal and permanent reduction of unwanted hair in Fitzpatrick skin types I – VI, including suntanned skin types.

III. Summary of Substantial Equivalence

Depilase believes that its DEPILASE YAG LASE PLUS Laser System is substantially equivalent to the Laserscope Lyra (K990718), and Altus Medical Aesthetic CoolGlide (K991798) Nd: YAG lasers, previously cleared for both the coagulation and haemostasis of vascular lesions and the removal and permanent reduction of unwanted hair in Fitzpatrick skin types I – VI, including suntanned skin types.

They therefore have the same Intended Use as the DEPILASE YAG LASE PLUS Laser System.

Technologically, the predicate devices have identical characteristics to the DEPILASE YAG LASE PLUS Laser System, all comprising a flashlamp pumped Nd: YAG laser rod generating light at a wavelength of 1064nm, which is subsequently delivered to the patient via an optical fibre delivery system and focusing handpiece.

The DEPILASE YAG LASE PLUS Laser System output characteristics are very similar to those of predicate devices.

All lasers are microprocessor controlled devices.

All lasers utilize Class I aiming beams which pose no hazard to the user.

All systems utilize an internal closed loop water-air heat exchange circuit for optimal thermal control of the laser cavity.

The risk and benefits of the DEPILASE YAG LASE PLUS Laser System are comparable to the predicate devices when used for similar clinical applications.

It is therefore believed that there are no new questions of Safety or Effectiveness raised by the introduction of this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 7 2002

Depilase Group Ltd.
c/o Ms. Pamela Gwynn
Engineering Team Leader
Underwriters Laboratories, Inc.
12 Laboratory Drive, P.O. Box 13995
Research Triangle Park, North Carolina 27709

Re: K020463
Trade/Device Name: DEPILASE YAG LASE PLUS Laser System
Regulation Number: 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: February 3, 2002
Received: February 12, 2002

Dear Ms. Gwynn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

APPENDIX F

INDICATIONS FOR USE STATEMENT

510 (K) Number (if known): K020463

Device Name: DEPILASE YAG LASE PLUS LASER SYSTEM

Indications For Use:

The DEPILASE YAG LASE PLUS Laser System is intended for the coagulation and haemostasis of vascular lesions and the removal and permanent reduction of unwanted hair in Fitzpatrick skin types I –VI, including suntanned skin types.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K020463

Prescription Use ✓ OR Over The Counter Use ____
(per 21 CFR 801.109)